GOVERNMENT OF INDIA
HEALTH AND FAMILY WELFARE
LOK SABHA

UNSTARRED QUESTION NO:3053
ANSWERED ON:23.08.2006
RENEWAL OF MANUFACTURING LICENCES .
Mohale Shri Punnulal

Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether Schedule M. Drugs and Cosmetics Act was introduced to improve the quality of export of drugs;

(b) if so, the details thereof;

(c) whether the Government has any proposal to renew the manufacturing licences of those units which are not exporting drugs;

(d) if so, the reasons therefor; and

(e) the number of units whose licences has not been renewed till date, State-wise?

Answer

THE MINISTER OF STATE IN THE MINISTRY OF HEALTH & FAMILY WELFARE (SMT. PANABAKA LAKSHMI)

(a) & (b) : The requirement of Good Manufacturing Practice (GMP) under Schedule 'M' of Drugs and Cosmetics Rules, 1945 was introduced in 1988 and revised in 2001 in order to assure improvement in Quality Assurance in manufacturing of drugs. The requirements of Schedule 'M' are not restricted to drugs manufactured for export as these are mandatory requirements for manufacturing of drugs by every drug manufacturing unit in the country.

(c)& (d) : The renewal of manufacturing licences is done as per norms prescribed under the Drugs and Cosmetics Rules, 1945. The renewal of licences is not linked with export of drugs.

(e) The renewal of manufacturing licenses is done by State Governments in accordance with existing norms. Data regarding number of licences renewed/not renewed by State Governments is not maintained centrally.